REMARKS

In the Office Action mailed December 9, 2008 from the United States Patent and Trademark Office, claims 1, 3-10, 12 and 13 under 35 U.S.C. 112. Accordingly, Applicant respectfully submits the following.

Written Description Rejections Under 35 U.S.C. §112, First Paragraph

In the Office Action mailed December 9, 2008 from the United States Patent and Trademark Office, claims 1, 3-10, 12 and 13 under 35 U.S.C. 112, first paragraph. In particular the pending action indicates that the terms "inhibit" and "inhibition" are not described in the specification in such a manner to clearly convey what is being claimed. Applicant respectfully notes that the terms "inhibit" and "inhibition" are commonly used in art to indicate interference with a chemical action or suppression of another substance (e.g., an enzyme). The terms are used ubiquitously in the art. As an example Applicant has attached copies of two pubmed.com book searches. One for "inhibit", which is referenced 2,491 times in the texts available on pubmed.com, and one for "inhibition", which is referenced 3,050 times in the texts available on pubmed.com. Applicant respectfully suggests that in view of the common use in the field the originally filed specification provide sufficient support to reasonably convey to one skilled in the art that the inventor of the present invention was in possession of the invention, namely a selective COX-2 inhibitor at the time the application was filed.

Evidence that Applicant was in possession of the claimed subject matter is provided in the originally filed specification, which discloses construction and use of the claimed embodiment. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter," where possession may be shown by describing testing of the claimed invention. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002). Applicant described testing of the claimed invention in the originally filed specification. In particular, Example 1 of the originally filed specification indicates that biochemical assays indicated that a concentration of 2.31% inhibited COX-1 by 20% and COX-2 by almost 60%, while a concentration of 10% *Morinda citrifolia* juice inhibited COX-1 approximately 83% and inhibited COX-2 approximately 84%. *Specification*, page 15, lines 1-5. The specification

further indicates that at greater concentrations the selective COX-2 inhibition properties experienced by administering *Morinda citrifolia* juice are sensitive or related to dosing. *Specification*, page 15, lines 5-15. Armed the knowledge of one skilled in the art, the present disclosure indicates that, appropriately dosed, the claimed concentration of *Morinda citrifolia* juice exhibits the unexpected effect of providing selective COX-2 inhibition, selective interference with the chemical action of COX-2 relative to the amount of selective interference with the chemical action of COX-1. Accordingly, the concept of inhibiting COX-2 relative to COX-1 is described and supported in the specification as originally filed, and Applicant respectfully requests that the §112 rejection be withdrawn at this time.

Enablement Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1, 3-10, 12 and 13 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent. However, to comply with 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system).

The enablement standard is a test of "whether one reasonably skilled in the art could make or use the invention from the disclosure of the patent coupled with information known in the art without undue experimentation." *In re Wands*, 858 F.2d 737 (Fed. Cir. 1988). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Further, the enablement standard is not an efficacy standard. "Testing for full safety and effectiveness ... is more properly left to the FDA." *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994). The specification need only explain how to make and use the invention without requiring an inordinate amount of experimentation. *In re Borkowski*, 422 F.2d 904 (C.C.P.A. 1970). The fact that experimentation may be complex does not necessarily make it undue if a person skilled in the art typically engages in such experimentation. *Id.* Further, compliance with the enablement requirement under §112, first paragraph, does not require or mandate that a specific example be disclosed. This specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art would be able to practice the invention without undue experimentation. *Id,* at 645.

The claims have been narrowed to recite a species of the formulation which is directly supported by the originally filed specification. The claims now recited a method for selectively inhibiting Cox-2 relative to Cox-1 comprising the steps of: administering a pre-determined dose of processed *Morinda citrifolia* juice to a patient at a concentration percentage of 2.31; and limiting undesired COX-1 inhibition relative to COX-2 inhibition. The specification provides enabling disclosure for the recited species indicating that, "[t]he biochemical assay results show that at a concentration of 2.31 percent, inhibition of the COX 1 cyclooxygenase was 20 percent, while inhibition of the COX 2 cyclooxygenase was almost 60 percent." *Specification*, page 15. One skilled in the art, utilizing the originally filed specification would certainly be enabled to make the claimed invention and use the claimed formulation by introducing into a mammal the claimed composition without requiring an inordinate amount of experimentation.

A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. MPEP § 2164.02. As indicated above, the specification provides a working example of administering a *Morinda citrifolia* product at both a concentration of 2.31% and 10%.

Further, the specification indicates multiply ways of making the processed *Morinda citrifolia* product of Claim 1. Beginning on page 8 and continuing until page 12, the specification provides a general discussion of *Morinda citrifolia* and the methods used to produce processed *Morinda citrifolia* products. The specification describes the noni plant known scientifically as *Morinda citrifolia L.* The specification describes methods of harvesting said *Morinda citrifolia.* Further, the specification provides methods for processing the *Morinda*

citrifolia product. Thus, the specification contains sufficient information to enable one skilled in the art to make a processed *Morinda citrifolia* product without undue experimentation.

The Specification also discloses a variety of ways in which a user could use or introduce a *Morinda citrifolia* based formulation to a mammal. Beginning on page 12, and continuing to page 17, the specification details preferred embodiments or modes of administering processed *Morinda citrifolia* products, including nine specific enabled embodiments for use of the claimed invention. Accordingly, the originally filed specification discloses a variety of ways in which a user could administer or use the claimed *Morinda citrifolia.*

Because the specification provides substantial detail regarding the methods for making and using the present invention, one reasonably skilled in the art would be able to make and use the invention from the disclosure of the patent, coupled with the information known in the art without undue experimentation. Accordingly, Applicant requests that the enablement rejection be withdrawn at this time.

CONCLUSION

Applicants submit that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,

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